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| 09/935,557 | 08/22/2001 | Erik Gunther | GUNE117293 | 8854 |
| 26389 | 7590 | 04/24/2007 | EXAMINER | |
| CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC | | | CLOW, LORI A | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--------------------------|------------------------|---------------------|--|
| Interview Summary | Application No. | Applicant(s) | |
| | 09/935,557 | GUNTHER, ERIK | |
| | Examiner | Art Unit | |
| | Lori A. Clow, Ph.D. | 1631 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) Lori A. Clow, Ph.D. (PTO). (3) _____.

(2) Tina Quintin (Apps. Rep.). (4) _____.

Date of Interview: 13 April 2007.

Type: a) Telephonic b) Video Conference
c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.
If Yes, brief description: _____.

Claim(s) discussed: All

Identification of prior art discussed: n/a.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant submitted proposed amendments to the claims. It was agreed that if the proposed amendments were submitted with no significant changes, that the amendments were sufficient to overcome the outstanding rejections of record.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Lori A. Clow 4/16/07
Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

SECRET

DISCUSSION ONLY
LAC

PROPOSED CLAIM AMENDMENTS: 09/935,557 (4/5/07)

*for discussion
purposes for interview
13 April 2007*

1. (Previously presented) A method for identifying analytes that induce a third expression profile that is more similar to a first expression profile than is a second expression profile, comprising:

(a) performing an assay to obtain a first expression profile of a set of representative molecules in a first biological sample;

(b) performing an assay to obtain a second expression profile of the set of molecules in a second biological sample, wherein the second biological sample differs from the first biological sample by a known parameter;

(c) performing an assay to obtain a third expression profile of the set of molecules in the second biological sample after treatment of the second biological sample with at least one analyte of previously uncharacterized specific pharmacological activity; and

(d) comparing the third expression profile with the first and second expression profiles to identify one or more analytes that induces a third expression profile that is more similar to the first expression profile than is the second expression profile, wherein the analytes identified as inducing a third expression profile that is more similar to the first expression profile than is a second expression profile is indicative of the identified analytes possessing pharmacological activity.

2. (Currently amended) The method of Claim 1, wherein step (d) comprises:

(a) deriving a first difference profile by comparing the first expression profile with the second expression profile;

(b) deriving a second difference profile by comparing the second expression profile with the third expression profile; and

(c) comparing the first difference profile with the second difference profile to identify the one or more analytes possessing pharmacological activity.

3. (Currently amended) The method of Claim 1, wherein identification of the one or more analytes with pharmacological activity comprises classifying all the expression profiles obtained in steps (a), (b) and (c) using neural network computing.

4. (Currently amended) The method of Claim 1, wherein any of the ~~steps used to perform the assay comprises use of assays~~ are performed using serial analysis of gene expression.

5. (Canceled)

6. (Original) The method of Claim 1, wherein the first or second biological sample is selected from one or more of the group of a specific cell type in vitro, a combination of cell types in vitro, a specific tissue type in vitro, a combination of tissue types in vitro, organs in vitro, a specific cell type in vivo, a combination of cell types in vivo, a specific tissue type in vivo, a combination of tissue types in vivo, organs in vivo, and an entire single-celled or multicellular organism.

7. (Previously presented) The method of Claim 1, wherein at least one biological sample is derived from a sample that exhibits a disease condition.

8. (Previously presented) The method of Claim 1, wherein the representative molecules are selected from the group consisting of mRNA

transcripts or cDNA derived therefrom, proteins, phosphoproteins, carbohydrates, and lipids.

9. (Currently amended) The method of Claim 1, wherein any of the ~~steps used to perform at least one of the assays comprises use of assays are performed using polynucleic acid microarrays.~~

10. (Previously presented) The method of Claim 9, wherein the polynucleic acid microarrays comprise elements capable of differentially binding specific peptides.

11. (Currently amended) The method of Claim 1, wherein ~~any steps used to perform performance of~~ at least one of the assays comprises simultaneously detecting the rates of transcriptions of multiple genes.

12. (Currently amended) The method of Claim 1, wherein ~~any steps used to perform at least one of the assays comprises use of the assays are performed using~~ capillary electrophoresis.

13. (Currently amended) The method of Claim 1, wherein ~~any steps used to perform at least one of the assays comprises use of the assays are performed using~~ 2-dimensional gel electrophoreses.

14. (Currently amended) The method of Claim 1, wherein ~~any steps used to perform at least one of the assays comprises use of the assays are performed using~~ one or more antibodies.

15. (Currently amended) The method of Claim 1, wherein ~~any steps used to perform at least one of the assays comprises use of the assays are performed using~~ spectrometry techniques.

16. (Original) The method of Claim 15, wherein the spectrometry technique is mass spectrometry.

17. (Currently amended) The method of Claim 1, wherein any steps used to perform at least one of the assays comprises use of the assays are performed using a method selected from the group consisting of fiber-optic, bead-based mRNA and protein detection.

18. (Currently amended) The method of Claim 1, wherein any steps used to perform at least one of the assays comprises use of the assays are performed using differential display.

19. (Previously presented) The method of Claim 1, wherein step (c) is conducted many times in high-throughput fashion with distinct analytes from a library of analytes.

20. (Previously presented) The method of Claim 1, wherein the first expression profile of step (a) is derived from a combination of biological samples.

21. (Original) The method of Claim 1, wherein the tested analyte of step (c) possesses previously characterized pharmacological activity unrelated to the parameter by which the first and second biological samples are known to differ, and where its pharmacological activity relative to said parameter is previously uncharacterized.

22. (Currently amended) The method of Claim 1, wherein any steps used to perform at least one of the assays comprises use of the assays are performed using chromatographic techniques.

23. (Original) The method of Claim 22, wherein the chromatographic technique is HPLC.

24. (Original) The method of Claim 22, wherein the chromatographic technique is gas chromatography.

25. (Currently amended) The method of Claim 1, wherein ~~any steps used to perform at least one of the assays comprises use of the assays are performed using~~ Western blotting.

26-31. (Canceled)

32. (Previously presented) A method for identifying analytes that induce a third expression profile that is more similar to a first expression profile than is a second expression profile, comprising:

(a) performing an assay to obtain a first expression profile of a set of representative molecules in a first biological sample;

(b) performing an assay to obtain a second expression profile of the set of molecules in a second biological sample, wherein the second biological sample differs from the first biological sample by exposure to a drug treatment;

(c) performing an assay to obtain a third expression profile of the set of molecules in a third biological sample after treatment of the third biological sample with at least one analyte of previously uncharacterized specific pharmacological activity with respect to the drug treatment to which the second biological sample was exposed; and

(d) comparing the third expression profile with the first and second expression profiles to identify one or more analytes that induces a third expression profile that is more similar to the first expression profile than is the second expression profile, wherein the analytes identified as inducing a third expression

profile that is more similar to the first expression profile than is the second expression profile is indicative of the identified analytes possessing pharmacological activity with respect to the drug treatment.

33. (Currently amended) The method of Claim 32, wherein identification of the one or more analytes with pharmacological activity with respect to the drug treatment comprises classifying all the expression profiles obtained in steps (a), (b) and (c) using neural network computing.

34. (Currently amended) The method of Claim 32, wherein any of the ~~steps used to perform at least one of the assays comprises use of assays are performed using serial analysis of gene expression.~~

35. (Previously presented) The method of Claim 32, wherein the biological sample is selected from one or more of the group of a specific cell type in vitro, a combination of cell types in vitro, a specific tissue type in vitro, a combination of tissue types in vitro, organs in vitro, a specific cell type in vivo, a combination of cell types in vivo, a specific tissue type in vivo, a combination of tissue types in vivo, organs in vivo, and an entire single-celled or multicellular organism.

36. (Currently amended) The method of Claim 32, wherein any of the ~~steps used to perform at least one of the assays comprises use of assays are performed using polynucleic acid microarrays.~~

37. (Previously presented) The method of Claim 32, wherein step (b) is conducted many times in high-throughput fashion with distinct analytes from a library of analytes.

38. (Previously presented) The method of Claim 1, wherein the representative molecules are mRNA transcripts.

39. (Previously presented) The method of Claim 1, wherein the representative molecules are cDNA derived from mRNA transcripts.

40. (Previously presented) The method of Claim 1, wherein the representative molecules are proteins.

41. (Previously presented) The method of Claim 1, wherein the representative molecules are phosphoproteins.

42. (Previously presented) The method of Claim 1, wherein the representative molecules are carbohydrates.

43. (Previously presented) The method of Claim 1, wherein the representative molecules are lipids.